

Remarks

Applicants hereby express their gratitude to Examiner Chereskin and SPE Weimar for the courtesy of the interview granted on October 13, 1993. Applicants wish to hereby make of record the substance of the interview:

- 1) No exhibits were presented nor demonstrations conducted.
- 2) All claims were discussed.
- 3) No prior art was discussed, as Applicants assert there is not significant, relevant prior art available to support any §102/§103 rejections.
- 4) Although the allowability of currently pending claims was discussed, Applicants also discussed the possibility of adding new claims which would be limited in scope to the specific nucleotide and amino acid sequences disclosed in the original specification, and claims limited to the specific plants exemplified in the original specification.
- 5) Applicants argued that the Examiner should withdraw the §112 rejections which are based on the Examiner's assertion that exemplification with one *B.t.* endotoxin nucleotide sequence does not enable one to use all *B.t.* endotoxin genes in the subject invention, despite Applicants' teachings to the contrary. In support of their position, Applicants argued that despite the varying sequence homology from one *B.t.* endotoxin gene to another, that all *B.t.* endotoxins share certain characteristics which cause those skilled in the art to look upon them as a class of proteins, which would be expected to be interchangeable for purposes of the subject invention. In addition, Applicants asserted that they are entitled to broad scope because of the pioneering nature of their invention, and the fact that they were as much as 1½-2 years ahead of anyone in disclosing this invention. The Examiner refused to admit the pioneering nature of the subject invention and expressed concern over the scope of the art which could be tied up by Applicants' claims, if allowed. Finally, Applicants argued that a claim directed to tobacco transformed to

express the nucleotide sequence depicted in Figure 1 of the original specification is clearly enabled and should be allowable.

- 6) Other pertinent matters discussed included the type and substantive content of possible declarations which Applicants could file in support of their arguments.
- 7) While no agreement was reached on allowability of claims, the Examiner did agree to consider any response and supporting declarations which Applicants might file.

Claims 15-44 and 46-52 are pending in the application. By way of this Amendment, Applicants have added new claims 53-56. Accordingly, claims 15-44 and 46-56 are currently before the Examiner.

Applicants respectfully traverse the §112 rejections set forth at pages 2-6 of the Office Action, and assert that their original application, filed September 26, 1983, is enabling. Applicants incorporate by reference as if fully set forth herein all arguments made in their last response in this application. In further support, Applicants submit herewith the Declaration of Dr. H.E. Schnepf (Schnepf Declaration) and the Second Declaration of Dr. Guy A. Cardineau (Second Cardineau Declaration). The Office Action correctly notes that Applicants have enabled the claimed invention for the *B.t.* endotoxin sequence shown in Figure 1. (Office Action page 2, lines 19-21). However, this particular endotoxin is merely a specific example of Applicants' broad, but explicit, teachings. The subject application teaches the skilled artisan that plants may be regenerated from plant cells which have been transformed to express *B.t.* endotoxin genes. In this regard, Applicants used the sequence of Figure 1 as an example to illustrate their broader teachings. While Applicants readily admit that some of the pending claims are broad in their scope, it is incontrovertible that Applicants teachings are equally broad in scope. As long as there is no prior art which would destroy the novelty of the claimed invention, the breadth of Applicants' teachings is an irrelevant concern. See *In re Marzocchi*, 439 F.2d 220,223 (CCPA 1971). "The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative

examples or by broad terminology, is of no importance." (underlining added) *Id.* "The only relevant concern of the Patent Office under these circumstances should be over the *truth* of any such assertion." (emphasis by the Court) *Id.*

There is insufficient prior art available to support any §102/§103 rejections based on the disclosure of Applicants' original application. Accordingly, with respect to the applicants' 1983 filing, under the authority of *In re Marzocchi, supra.*, the breadth of Applicants' teachings is an irrelevant concern. The only relevant concern is whether they are true. The Schnepf Declaration addresses the enablement issues raised by the Examiner regarding the scope of *B.t.* endotoxin genes taught and claimed to be useful in the subject invention, and explains why the skilled artisan would accept applicants' teachings in this regard as true. The Cardineau Declaration verifies that teachings of the original application, if followed by the skilled artisan, yield transgenic insecticidal plants, as exemplified by tobacco. Thus the original application is proven to be enabling.

The Schnepf Declaration is thus evidence supporting the truth of Applicants' teachings regarding the usefulness of the broad class of *B.t.* endotoxin genes in the claimed invention. Dr. Schnepf lucidly explains why one skilled in the art would expect *B.t.* endotoxin genes to be relatively interchangeable in the claimed invention, with any difficulties being expected to correlate with gene length rather than the type of insecticidal activity characterizing the protein encoded by such genes. As Applicants have exemplified a *B.t.* endotoxin gene at the long end of the spectrum and taught that other, including shorter, *B.t.* nucleotide sequences will also work, there is no reasonable basis for the skilled artisan to doubt Applicants' teachings. The Second Cardineau Declaration proves that plants transformed to express nucleotide sequences of varying length are enabled. Accordingly, reconsideration is respectfully requested.

Applicants traverse the §112, first paragraph rejections set forth at pages 6-7 of the Office Action. Applicants note the Examiner's acknowledgement at page 6, lines 10-11, that the disclosure is enabling for claims limited to dicot cells. The Second Cardineau Declaration sets forth the evidence confirming Applicants' argument that their 1983 filing is enabling. Although Applicants believe that they are entitled to claims not limited to transformed dicot species, Applicants note that there are a number of claims currently pending which are so limited. For

example, see claims 27, 30-32, 50, and claims dependent therefrom. In view of the Schnepf Declaration, the Cardineau Declarations of record, and the Examiner's acknowledgement that the Applicants' disclosure is enabling for claims limited to dicot cells, Applicants respectfully assert that these claims are allowable. Reconsideration is accordingly requested.

In response to the §112, first paragraph rejection set forth at pages 7-8 of the Office Action, Applicants again refer the Examiner to the Schnepf and Cardineau Declarations. Contrary to what is stated in the Office Action, *B.t.* endotoxins other than that exemplified in the specification have similarities beyond that fact that they are toxin to insects. The Schnepf Declaration clearly describes the similarities. *B.t.* endotoxins are recognized in the art as a class of proteins, and the skilled artisan would expect that the genes encoding these endotoxins would be interchangeable for purposes of the subject invention.

If the Examiner's rejection is based in part on the concern that *B.t.* endotoxin genes which have been discovered since Applicants' original filing exhibit increasingly varying degrees of homology from those which had been characterized prior to the subject invention, Applicants have two responses. First, these later-discovered genes are readily recognized by those skilled in the art as belonging to the class of genes encoding *B.t.* endotoxins, and accordingly would be expected to work in the subject invention for the reasons set forth in the Schnepf Declaration. The fact that new genes continue to be discovered does not detract from truth or strength of Applicants' assertions that *B.t.* endotoxin genes have been sufficiently exemplified in the original specification and that other *B.t.* endotoxin genes would be expected to work in the subject invention. Second, if the Examiner's rejection is based on a concern that later-discovered genes might be encompassed within the scope of Applicants' claims, Applicants believe that this is an inquiry concerning what would infringe their pending claims, rather than whether those claims are patentable. Applicants believe that later-discovered genes would be expected to work in the subject invention by virtue of the fact that they are *B.t.* genes and that they are recognized as belonging in the class of genes encoding *B.t.* endotoxins. Accordingly, Applicants believe that there is nothing wrong with such genes being within the scope of their claims. It is important to note that, as the Court of Customs and Patent Appeals has stated:

"The business of the PTO is patentability not infringement. Like the judicially-developed doctrine of equivalents designed to protect the patentee with respect to later-developed variations of the claimed invention, the judicially-developed 'reverse doctrine of equivalents', requiring interpretation of claims in light of the specification, may be safely relied upon to preclude *improper* enforcement against later developers. The courts have consistently considered subsequently existing states of the art as raising questions of infringement, but never of validity. It is, of course, a major and infinitely important function of the PTO to insure that those skilled in the art are enabled, as of the filing date, to practice the invention claimed. If, in the light of all proper evidence, the invention claimed be clearly enabled as of *that* date, the inquiry under §112, first paragraph, is at an end." (underlining added, italics in the original). *In re Hogan*, 559 F.2d 595, 607 (CCPA 1977).

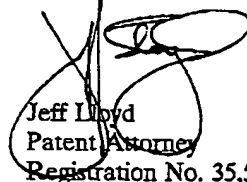
Although the prosecution history reflects the Examiner's doubt as to whether all *B.t.* endotoxin genes of every class would work in the subject invention, Applicants believe that it is uncontroverted that all *B.t.* endotoxin genes which had been characterized prior to September 26, 1983 would have been expected by the skilled artisan to work as taught. Under *In re Hogan*, this is sufficient. Reconsideration is respectfully requested.

Finally, Applicants traverse all of the §102 and §103 rejections set forth at pages 8-13 of the Office Action. None of the primary references cited has an effective date earlier than 1986, almost three years after the September 26, 1983 filing date of Applicants' original specification. Applicants reassert their entitlement to the benefit of that filing date for all pending claims, and incorporate herein by reference their arguments for priority which were set forth in portions of pages 9-16 of the April 13, 1992 Preliminary Amendment filed herein. If the primary references are unavailable, these rejections cannot stand. Applicants once again note that their original application, at pages 37-39, specifically exemplifies the shortened *B.t.* gene encoding a protein of approximately 90 to 105 kD, (see also Figure 1), which is later proteolytically cleaved to yield an insecticidal fragment of approximately 68 kD (see Second Cardineau Declaration). Accordingly, claims encompassing a shortened gene are entitled to the filing date of the original application. In view of the foregoing, Applicants believe that all claims as currently pending are in condition for allowance and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

Applicants urge the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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JL/srp

Attachments: Second Declaration of Dr. Guy Cardineau
Declaration of Dr. H. Ernest Schnepf

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